DETAILED ACTION

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because **a)** the lines, numbers and letters are not uniform, clean and well defined (of a generally poor quality) in **Figures 4A, 4B, 5A, and 5B** (37 CFR 1.84(l)). Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7, and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Knowlton (5,660,836).

Regarding claim 1, Knowlton discloses an apparatus comprising generating means (28) for generating radio-frequency electromagnetic radiation, connectable to application means (26, see Fig. 1) for the application of said radiation to a skin portion of a human body, said application means comprising an active electrode (26) and a reference electrode (return electrode, col. 5, lines 33-37), said active electrode having a

skin contact surface (12), said active electrode being provided with a sensor means (52) for the detection of skin temperature of the skin portion, said sensor means including at least a sensor incorporated (col. 6, lines 17-23) in said active electrode, wherein said active electrode is a plate shaped electrode (Fig. 1 shows a plate shaped RF electrode 26).

Regarding claim 5, Knowlton discloses an apparatus according to claim 1, wherein said means for the detection of the skin's temperature are connected to a control circuit connectable to and acting on said generating means for radio-frequency radiation (col. 7, lines 65-67 and col. 8, lines 1-3).

Regarding claim 7, Knowlton discloses structure of the active electrode is complementary shaped with respect to the skin portion of the human body region of the patient to be treated (Fig. 1 shows a plate shaped RF electrode 26).

Regarding claim 9, Knowlton discloses an apparatus according to claim 1, further comprising additional active electrodes connected to a switch device able to connect in sequence said active electrodes to said generating means for generating radio-frequency radiation (col. 8, lines 19-27).

Regarding claims 10 and 12, Knowlton discloses an apparatus according to claim 1, further comprising means for adjusting the temperature reached on the skin and able to vary the output power in order to keep skin temperature at a preset value (col. 7, lines 65-67; and col. 8, lines 1-8).

Regarding claim 11, Knowlton discloses an apparatus according to claim 1, wherein further comprising measuring means for measuring the output power and the impedance in correspondence of the application means (col. 8, lines 2-13).

Regarding claim 13, Knowlton discloses an apparatus according to claim 1, further comprising means for connection with an electronic processor (#84; col. 8, lines 28-46).

Regarding claim 14, Knowlton discloses an apparatus comprising: generating means (28) for generating radio-frequency electromagnetic radiation; and application means (26, see Fig. 1) connected to said generating means for the application of said radiation to a skin portion of a human body, said application means comprising an active electrode (26) and a reference electrode (return electrode, col. 5, lines 33-37), said active electrode being provided with a skin temperature sensor (52) means for the detection of skin temperature of the skin portion, said sensor means including at least a sensor part directly incorporated (col. 6, lines 17-23) in or directly connected to said active electrode.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Wiksell et al. (4,846,196).

Wiksell et al. disclose an apparatus for non-destructive hyperthermia therapies (abstract), the apparatus comprising: generating means for generating radio-frequency electromagnetic radiation; and application means connected to said generating means for the application of said radiation to a skin portion of a human body (abstract), said

application means comprising an active electrode and a reference electrode (Fig. 1, #2, #6), said active electrode being provided with a skin temperature sensor means for the detection of skin temperature of the skin portion (column 9, lines 50-51), said sensor means including at least a sensor part directly incorporated in or directly connected to said active electrode (column 7, lines 26-28 and column 9, lines 50-51).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton in view of Rittman, III et al. (US 6,506,189 B1).

Knowlton discloses the claimed invention except for an apparatus according to claim 1, wherein said sensor means for the detection of the skin's temperature comprises a sensor which can be connected to the apparatus and removably associated with the active electrode, said active electrode having a seat complementarily matching a corresponding connector of the sensor.

However, Rittman, III et al. teach in the past, RF ablation electrodes have incorporated temperature sensors (column 1, lines 42-44).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a removable temperature sensor as taught by Rittman, III et al., since by providing temperature sensor in a removable form, its failure will not likely compromise the operation of the device (col. 7, lines 52-57).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton in view of Doss et al. (4,016,886).

Knowlton discloses the claimed invention except for an apparatus according to claim 1, wherein said reference electrode has dimensions larger than those of the active electrode.

However, Doss et al. teach a small electrode 12 is placed directly over the tumor volume while larger remote electrode 13 provides a return path to oscillator 11 (col. 3, lines 59-63).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a larger return electrode as taught by Doss et al., since Doss et al. states at column 3 lines 63-68 and column 4 lines 1-5 that by employing different relative electrode areas, since the same current flows through each electrode surface, current density is higher adjacent to the smaller electrode 12. Therefore the temperature rise in the region of the smaller electrode 12 is greater. This treatment approach is most useful in those cases where the treatment volume is at least partially convex from the normal body surface and where there is a minimal amount of fat between the electrode surface and the tumor volume.

Response to Arguments

Applicant's arguments filed March 10, 2008 with respect to claims 1, 4, 5, and 7-14 have been considered but are moot in view of the new ground(s) of rejection.

The Examiner has withdrawn the claim objection.

In response to applicant's argument that the prior art as a whole fails to provide such advantages such as treating rheumatoid inflammations, tendonitises and acute inflammatory forms from a location outside of the living being's skin without damaging or burning the skin, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Furthermore, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham, 2 USPQ F.2d 1647 (1987).*

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6743226 B2; US 5003991 A; and US 4798215 A.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John R. Di Cicco whose telephone number is (571) 270-5039. The examiner can normally be reached on M-Th 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John R. Di Cicco/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739